DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 10, 2014

Honeywell Hommed
Claudia Jackson
Regulatory Affairs Specialist
3400 West Intertech Drive
Brookfield, Wisconsin 53045

Re: K141792
Trade/Device Name: Genesis Touch System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: October 21, 2014
Received: October 22, 2014

Dear Claudia Jackson,

This letter corrects our undated substantially equivalent letter.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Honeywell HomMed Genesis Touch System

Indications For Use:

The Honeywell HomMed Genesis Touch™ Retrospective Physiological Monitoring System is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse oximetry, pulse rate, weight, temperature, blood sugar, prothrombin time/international normalized ratio (PT/INR), peak expiratory flow (PEF) and forced expiratory volume (FEV1). The Genesis Touch Retrospective Physiological Monitoring System collects; displays and transmits vital signs measurements from commercially available medical devices designed for home use. Collected measurement data from the Genesis Touch System can then be transmitted via a communication module to a central viewing station where the data can be viewed and analyzed by a healthcare professional.

The Genesis Touch Retrospective Physiological Monitoring System is intended for home use by patients and caregivers or in a healthcare related environment by healthcare providers.

The Genesis Touch Retrospective Physiological Monitoring System is not intended for emergency use or real-time monitoring and does not have auditory or visual alarms for out-of-limit parameters.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary as required by section 807.92(c)
Honeywell HomMed Genesis Touch™ System

Applicant Name: Honeywell HomMed, LLC.

Address: 3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045
Ph: (262) 252-783-5440
Establishment Registration #3004183721

Summary Date: 06/25/2014

Contact Person: Claudia Jackson, Regulatory Affairs Specialist
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Corporate Contact: Greg Lillegard, Director of Quality
Honeywell HomMed, LLC
Ph: (262) 252-262-6062
Fax: (262)252-262-6119

Trade Name: Honeywell HomMed Genesis Touch System

Common Name: Patient Vital Signs Monitor

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Radiofrequency Physiological Signal Transmitter and Receiver	II
Medical device product codes also supported by Genesis Touch by means of separate medical devices			
870.1130	DXN	Noninvasive Blood Pressure Measurement System	II
880.2700	FRI	Patient Weight Scale	I
870.2700	DQA	Oximeter	II
862.1345	NBW	Glucose Test System	II
868.1860	BZH	Meter, Peak Flow, Spirometry	II
864.7750	GJS	Test, Time, Prothrombin	II

Predicate Device(s): Honeywell HomMed Genesis DM Pro BP, K101242;
Honeywell HomMed Genesis Touch System, K112858

510(k) Summary

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Device Description:

The modified Honeywell HomMed Genesis Touch™ Retrospective Physiological Monitoring System (Genesis Touch™ System) is a vital signs monitoring station.

The modified Genesis Touch System is a proprietary software application running on a dedicated software/commercially available tablet platform with touch screen; Wi-Fi, Bluetooth and video capability.

The modified Genesis Touch System uses text and voice prompts to collect users' vital signs information from paired Bluetooth noninvasive medical device peripherals, such as blood pressure, pulse oximetry, pulse rate, weight, temperature, blood sugar, and allows for manual entry of blood sugar, prothrombin time/international normalized ratio (PT/INR), peak expiratory flow (PEF) and forced expiratory volume (FEV1). The encrypted data is automatically or at the user's discretion, forwarded to a remote central monitoring station (Honeywell HomMed LifeStream Management Suite) for retrospective review by healthcare providers.

LifeStream Management Suite, a Windows-based application interface is used by the healthcare provider for the remote configuration of all the Genesis monitors, triaging of patient data, trending of clinical information, and the opportunity to provide preventative patient care.

The modified Genesis Touch System also asks the user disease specific symptom management questions and provides reminder information, just like the predicates Genesis DM and Genesis Touch System. Both the modified Genesis Touch System and predicate Genesis Touch System, offer animated video instructions and optional one-touch, video-based communication in addition to traditional telemonitoring.

The modified Genesis Touch monitor expands the user population to include patients and caregivers willing and capable of managing its use. The modified Genesis Touch System is a touch screen tablet with a consumer-based Android platform like the predicate Genesis Touch System. This type of user interface is easily usable by a wider age and acuity range. The user population of the predicate monitors, Genesis Touch System and Genesis DM Monitor are designated for use with adult and pediatric patients over twelve years of age. The expanded user population of the modified Genesis Touch System is presented in order to compliment the user population of interfaced peripheral medical devices which do not limit the user population to being over twelve years of age. This modification does not change the intended use of the modified Genesis Touch System as a communication hub that collects; displays and transmits vital signs data from noninvasive medical device peripherals via a communication module to a central viewing station for retrospective review by a healthcare professional. This modification does not affect the safety and effectiveness of the Genesis Touch System when used as labeled.

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Indications for Use:

The Honeywell HomMed Genesis Touch™ Retrospective Physiological Monitoring System is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse oximetry, pulse rate, weight, temperature, blood sugar, prothrombin time/international normalized ratio (PT/INR), peak expiratory flow (PEF) and forced expiratory volume (FEV1). The Genesis Touch Retrospective Physiological Monitoring System collects; displays and transmits vital signs measurements from commercially available medical devices designed for home use. Collected measurement data from the Genesis Touch System can then be transmitted via a communication module to a central viewing station where the data can be viewed and analyzed by a healthcare professional.

The Genesis Touch Retrospective Physiological Monitoring System is intended for home use by patients and caregivers or in a healthcare related environment by healthcare providers.

The Genesis Touch Retrospective Physiological Monitoring System is not intended for emergency use or real-time monitoring and does not have auditory or visual alarms for out-of-limit parameters.

Technological Characteristics:

The modified Genesis Touch Retrospective Physiological Monitoring System (Genesis Touch System) is substantially equivalent to the predicate devices, Honeywell HomMed Genesis DM and Honeywell HomMed Genesis Touch System as a proprietary software application running on a dedicated software/hardware platform, with the function of data collection, data display, data transmission, and data communication from noninvasive peripheral medical device types to a central server. The predicate Genesis DM uses hard button push keys to advance menu selection, selection of vitals collection, and provide responses while the modified Genesis Touch System and predicate Genesis Touch System both use graphic icon touch keys to accomplish the same tasks.

The modified Genesis Touch System and the predicate Genesis Touch System are proprietary software applications operating on a dedicated commercially available tablet platform with the minimum performance specifications consistent with typical tablet computer hardware and equipment specifications. The modified Genesis Touch System and the predicate Genesis Touch offers a touch screen user interface; Wi-Fi, Bluetooth and video capability.

The predicate Genesis DM is a monitoring system with proprietary firmware which operates in a dedicated hardware design.

The modified Genesis Touch System application and both predicate devices, Genesis DM, and Genesis Touch System, restrict, or “locks down”, the system’s functionality such that the user cannot install other programs, nor use the device for any other purpose other than the intended use.

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The modified Genesis Touch System and the predicate, Genesis Touch System both have the ability to collect vital signs data via wireless technology (Bluetooth) or manually, while the predicate Genesis DM Monitor collects vital signs data using both wireless (Bluetooth) and wired technology. The predicate Genesis DM Monitor collects; displays and transmits the vital signs for noninvasive blood pressure, pulse oximetry, pulse rate, weight and temperature with the option to connect to peripheral medical devices and collect vital signs data for blood sugar, prothrombin time/international normalized ratio (PT/INR), peak expiratory flow (PEF) and forced expiratory volume (FEV1). The predicate Genesis Touch System collects; displays and transmits the vital signs for noninvasive blood pressure, pulse oximetry, pulse rate, weight and manually entered temperature. The modified Genesis Touch System combines the physiological parameters collected, displayed and transmitted by both of the predicates to include, noninvasive blood pressure, pulse oximetry, pulse rate, weight, temperature, blood sugar, prothrombin time/international normalized ratio (PT/INR), peak expiratory flow (PEF) and forced expiratory volume (FEV1).

The functionality of the modified Genesis Touch System is substantially equivalent to the predicates Genesis Touch System and Honeywell HomMed Genesis DM Monitor such that all of the monitors use text and voice prompts to collect users' vital signs or upload data from peripheral medical devices, and then forward that data to a remote central monitoring station for retrospective review by a healthcare professional. All of the monitors are designed for home use or in a healthcare related environment. The monitors are not intended for emergency use or real-time monitoring and do not have auditory or visual alarms for out-of-limit parameters.

Performance (Non-clinical) Data:

The modified Genesis Touch System is a software application loaded onto a commercially available tablet, therefore no electrical safety or electromagnetic testing is required. Risk based verification and validation testing was performed in accordance with the FDA guidance's, "General Principles of Software Validation". Verification, validation and regression testing of the existing and new feature presented for the modified Genesis Touch System, ensured that the software met performance and functional specifications for usability, hardware and software interoperability, data transfer, accuracy, display and transmission, system reliability, availability and serviceability.

Conclusion

The verification, validation, and regression testing performed on the modified Genesis Touch System did not raise any new issues of safety or efficacy and demonstrated that the modified Genesis Touch System performs safely, effectively, and correctly in accordance with specifications and labeling claims as intended and was found to perform as well as or better than the predicate devices, Genesis Touch System and Genesis DM Monitor.

Based on the intended use and performance results, the modified Genesis Touch System has been shown to be substantially equivalent to the predicate devices.

510(k) Summary